K122816

OCT 9 2012

COOK ENDOSCOPY
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510(k) Summary

Sponsor:	Wilson-Cook Medical, Inc/Cook Endoscopy 4900 Bethania Station Road Winston-Salem, NC 27105
Contact/Submitter:	Doris A. Hawks Global Regulatory Affairs Specialist Phone: (336) 744-0157 Ext. 6293 Fax: (336) 201-5994 e-mail: doris.hawks@cookmedical.com
Date of Submission	
Trade Name:	Axcess Soft Tip Wire Guide
Common Name:	Wire Guide
Classification:	Endoscope Guidewire, Gastroenterology-Urology, Class II 21 CFR § 876.1500 78 OCY
Predicate Device:	Wilson-Cook Tracer Metro Smart Wire Guide (k033754)
Intended Use:	Intended to assist in cannulation of the biliary and pancreatic ducts and to aid in bridging difficult strictures during ERCP.
Device Description:	The proposed Endoscopic Wire Guide is a modification to existing wire guides currently marketed by Wilson-Cook Medical, Inc. The Endoscopic Wire Guide is .025" in diameter and is compatible with a full range of Wilson-Cook accessories.
Comparison of Characteristics:	We believe the proposed device to be substantially equivalent to the currently market predicate device cleared via k033754.
Performance Data:	We believe risks associated with the modifications to the subject device to be adequately addressed through our Design Control Processes. We believe the proposed device to be substantially equivalent to the named predicate in terms of its intended use, performance characteristics tested and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Doris A. Hawks
Global Regulatory Affairs Specialist
Wilson-Cook Medical, Inc.
4900 Bethania Station Road
WINSTON-SALEM NC 27105

OCT 9 2012

Re: K122816
Trade/Device Name: Endoscopic Wire Guide
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: September 13, 2012
Received: September 14, 2012

Dear Ms. Hawks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122816

Device Name: Endoscopic Wire Guide

Indications for Use:

This device is intended to assist in cannulation of the biliary and pancreatic ducts and to aid in bridging difficult strictures during ERCP

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122816